**Docket # 99N-4166**
**OMB Number 0910-0303**

**SUPPORTING STATEMENT FOR**

**Electronic Records; Electronic Signatures -**
**21 CFR Part 11**
**OMB No. 0910-0303**

## A. JUSTIFICATION

### 1. Circumstance Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting an extension of the information collection requirements contained in 21 CFR Part 11, OMB No. 0910-0303, Electronic Records; Electronic Signatures (ESIG).

Part 11 establishes conditions for the elective use of electronic records and signatures. These conditions include certain procedures and controls to ensure the authenticity, integrity, and when appropriate, the confidentiality of electronic records and to ensure that the signer cannot readily repudiate the signed record as not genuine.

Specifically, the recordkeeping provisions in part 11 (sections 11.10, 11.30, 11.50, and 11.300) require standard operating procedures (SOPs) to ensure appropriate use of, and precautions for, systems using electronic records and signatures. While some of the procedures and controls may be built into a system, others will require SOPs and one specifically requires the establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures in order to deter record and signature falsification. Many of the procedures and controls are now standard in regulated industry and routinely used in order to protect electronic records and documents (i.e., personnel information, internal communications and discussions, and confidential and trade secret information).

The requirements for this information collection are as follows:

| | | |
|---|---|---|
| 21 CFR 11.10 | Recordkeeping | Specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records. Some or all of these procedures and controls will need to be incorporated in SOPs. |



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| | | |
|---|---|---|
| 21 CFR 11.30 | Recordkeeping | Specifies procedures and controls for persons who use open systems to create, modify, maintain or transmit electronic records. Some or all of these procedures and controls will need to be incorporated in SOPs. |
| 21 CFR 11.50 | Recordkeeping | Specifies procedures and controls for persons who use electronic signatures. Some or all of these procedures and controls will need to be incorporated in SOPs. |
| 21 CFR 11.300 | Recordkeeping | Specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. Some or all of these controls will need to be incorporated in SOPs. |

2. **Purpose and Use of the Information**

This recordkeeping is intended to permit the widest possible use of electronic technology compatible with FDA's responsibility to promote and protect public health. The procedures and controls defined in SOPs are intended for use by the organizations that develop them. The purpose of the SOPs are to ensure that organizations adopt procedures for appropriate and secure use of electronic systems. Because widespread use of electronic technology is relatively recent, the significance of official, legally binding electronic records may not be fully appreciated by everyone.

3. **Use of Information Technology**

The purpose of the ESIG regulation is to permit widespread use of information technology by the regulated industry for all FDA reporting and recordkeeping requirements.

4. **Efforts to Identify Duplication**

The ESIG regulation permits, for the first time, FDA-mandated records and signatures to be created and maintained electronically. This permits widespread use of a technology not contemplated when most reporting and recordkeeping requirements were issued. To create the required SOPs, many organizations will be able to simply describe procedures and controls already adopted internally to protect the authenticity, integrity, and

confidentiality of electronic data, records, and signatures.

5. **Impact on Small Business**

The regulation is expected to have a positive impact on nearly all organizations subject to the rule, including small business. For example, within the medical device industry alone, 93% of the firms are small business (i.e., have fewer than 500 employees). It is estimated also that approximately 500 pharmaceutical firms are small business. Of the approximately 3,000 registered blood and plasma establishments that are neither government owned nor part of the Red Cross, most are nonprofit establishments that are not nationally dominant and thus may be small entities.

Although the capability for making electronic submissions to FDA will be phased in over time, firms can benefit immediately by using ESIG for records they are required to keep, but not submit to FDA. Such records include, but are not limited to: pharmaceutical and medical device batch production records, complaint records, and food processing records.

Because it will increase the market demand for certain types of software (e.g., document management, signature, and encryption software) and services (e.g., digital notaries and digital signature certification authorities), this rule benefits some small firms engaged in developing and providing these products and services.

In addition, a small business coordinator within the agency works to ensure that small businesses have an adequate opportunity to express their concerns and to keep FDA management apprised of how regulatory decisions might impact the small business community.

6. **Consequences of Collecting the Information Less Frequently**

The prescribed frequency for the collection of information is based upon FDA's statutory responsibility to ensure the availability of uniformly high quality products to the nation. FDA ensures compliance with many recordkeeping requirements by conducting establishment inspections, as authorized by section 704 (21 U.S.C. 374) of the Federal Food, Drug, and Cosmetic Act, to review and evaluate the adequacy of records. It is widely recognized that certain procedures and controls are necessary to protect the integrity of electronic records. As a result, FDA believes it is necessary to establish SOPs incorporating the procedures and controls provided in the rule. As noted, many organizations recognize the need to protect the integrity of their electronic systems and have adopted identical or similar procedures and controls.

7. **Special Information Collection Circumstances**

These recordkeeping requirements deviate from the specification of 5 CFR 1320.6 in one respect. A person engaged in drug product manufacturing operations is required to retain records specifically associated with a drug product for at least 1 year after the expiration date or, in the case of certain OTC drug products lacking expiration dating, 3 years after distribution of the last lot of drug product (21 CFR 211.180). Depending on the approved dating period or shelf life of the drug product, it is possible that records would be retained for more than 3 years. Availability of these records provide an opportunity to follow up on complaints and adverse reports received during a drug's marketing period. Failure to have these records available for an investigation could prevent the resolution of undesirable and potentially life-threatening conditions. Audit trails are electronic records that must be kept, per §11.10(e), for at least as long as the related subject records.

8. **Outside Consultation**

In accordance with 5 CFR 1320.8(d), on October 1, 1999 (64 FR 53392), FDA provided an opportunity for public comment on a proposed collection of information. Comments from five respondents were received. In general, these comments addressed the costs of complying with technical provisions of 21 CFR Part 11 or used the opportunity as a forum to comment on the outcome of the final rule. Seven of these comments addressed the information collection and in general, asserted that FDA had either underestimated burden or had not considered all of the reporting and recordkeeping requirements. The comments on the information collection are addressed below.

One comment submitted by industry stated that the creation of standard operating procedures (SOPs) is not a one-time burden. It believes that the SOPs must be periodically reviewed and revised. FDA only requires the development of SOPs. FDA acknowledges that SOPs may need to be updated from time to time, but not necessarily because of a FDA requirement. If industry chooses to change their internal operations, then the associated change/update to the SOPs is a result of the company's choice to make changes, not a result of FDA requiring the change. Should SOPs need to be modified as a result of future changes to FDA regulations, FDA will consider the associated information collection burdens at the time it revises the relevant regulations.

One comment asserted that the issuance of guidance documents further defines the expectations of FDA and, as such, requires industry to modify procedures and systems to reflect these new expectations. FDA recognizes that guidance documents may have additional reporting or recordkeeping requirements, however, the associated burden will be tied to the specific guidance document, and is not a part of this information collection. FDA will separately submit to OMB for review and clearance, any additional proposed collection of information associated with guidances.

One comment stated that the regulation required industry to provide FDA with copies of software, as well as data. The comment added that this "requirement" places industry in the position of violating or renegotiating license agreements in order to comply with 21 CFR Part 11. 21 CFR Part 11 does not require companies to provide FDA with copies of software to access their records.

One comment asserted that FDA had ignored the burden in 21 CFR Part 11 that requires industry to maintain records in electronic format for the full retention period. Electronic records must be archived under 21 CFR Part 11 for the same period applicable regulations say the equivalent paper record must be archived. The burden for archiving the records, in whatever form, is accounted for in the applicable FDA regulations.

Two comments addressed the requirement for certificates. While reviewing these comments, FDA realized that under 5 CFR 1320.3 (h)(1), "affidavits, oaths, affirmations, certifications, receipts, changes of address, consents, or acknowledgments" are not deemed to constitute a collection of information. Therefore, the reference to the certificates and the associated burden have been removed.

One comment stated that its internal bureaucracy is such that it takes a long time to develop and approve a simple SOP, and therefore, FDA's estimate of cost was inaccurate. FDA has estimated the average annual burden. It will take some respondents more time and some less to develop and approve a SOP.

9. **Payment or Gift**

No payment or gift will be provided to respondents.

10. **Confidentiality Provisions**

The agency frequently handles confidential information. Confidentiality is maintained over trade secret, proprietary, or confidential, commercial or financial information under 21 CFR 20.61 and investigatory records under 21 CFR 20.64. In addition, certain subparagraphs of 21 CFR 314.430 and 514.11 provide confidentiality of information contained in new drug applications (NDA's), abbreviated new drug applications (ANDAs), and new animal drug applications (NADAs). Many of the provisions of part

11 are designed to preserve confidentiality when using electronic systems. This goal is one of the stated purposes of the procedures and controls provided in the regulation.

11. **Privacy**

There are no recordkeeping requirements regarding sexual behavior and attitudes, religious beliefs, or any other matters which are commonly considered private or sensitive in nature.

12. **Burden Hours**

a. Hourly Burden

Estimated Annual Recordkeeping Burden

| 21 CFR Section | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 21 CFR 11.10 | 2,250 | 1 | 2,250 | 20 | 45,000 |
| 21 CFR 11.30 | 2,250 | 1 | 2,250 | 20 | 45,000 |
| 21 CFR 11.50 | 4,500 | 1 | 4,500 | 20 | 90,000 |
| 21 CFR 11.300 | 4,500 | 1 | 4,500 | 20 | 90,000 |
| Total | | | | | 270,000 |

The burden created by this regulation is a one-time burden associated with the creation of standard operating procedures and validation. The agency anticipates the use of electronic media will reduce substantially the paperwork burden associated with maintaining FDA required records.

The respondents will be businesses and other for-profit organizations, state or local governments, Federal agencies and nonprofit institutions.

There are no capital costs or operating and maintenance costs associated with this collection of information.

b. Estimated Annualized Cost to Respondents

The estimated annualized cost to respondents is $9,204,975. The cost to respondents is estimated on the time required to compile information

that already exists into SOPs and to compile a one-paragraph certification. This generally requires one professional specialty person at an adjusted pay rate of $39.66 per hour (270,000 hours x 3/4 hour x $39.66 = $8,031,150) and administrative support staff at an adjusted pay rate of $17.39 per hour (270,000 hours x 1/4 hour x $17.39 = $1,173,975). These salary estimates include compensation but no overhead costs.

13. **Estimate of Other Total Annual Cost to Respondents or Recordkeepers**

There are no significant capital costs associated with the collection of information under 21 CFR part 11.

14. **Annualized Cost to the Federal Government**

There are no costs to the Federal Government.

15. **Explanation for Program Changes or Adjustments**

The burden increase is due to the anticipated increase in the number of registrants. As the opportunity to submit and maintain documents electronically becomes more available to the public, the number of registrants is expected to increase.

16. **Publication of Information Collection Results**

FDA does not intend to publish the results of the information collection required by these regulations.

17. **Display of OMB Approval Date**

There are no forms associated with this collection.

18. **Exceptions to Certification for Paperwork Reduction Act Submissions**

As stated in Item 7, there are instances where the respondents will be required to keep records longer than three years. There are no other exceptions to the "Certification for Paperwork Reduction Act Submissions" for this request.